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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/551,162

09/28/2005

Stan Gronthos

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23432 7590 06/22/2009

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EXAMINER

BELYAVSKIY, MICHAEL A

ART UNIT

PAPER NUMBER

1644

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/551,162	<b>Applicant(s)</b> GRONTHOS ET AL.	
	<b>Examiner</b> Michail A. Belyavskyi	<b>Art Unit</b> 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 March 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 68-106 is/are pending in the application.
- 4a) Of the above claim(s) 82-106 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 68-81 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>03/17/09; 06/05/09</u> .                                      | 6) <input type="checkbox"/> Other: _____                          |

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RESPONSE TO APPLICANT'S AMENDMENT

1. Applicant's amendment, filed 03/17/09 is acknowledged.

Claims 68-106 are pending.

2. Claims 82-106 stand withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b) as being drawn to nonelected inventions.

*Claims 68-81 read on an enriched cell population of mesenchymal precursor cells, enriched for 3G5 positive cells.*

In view of the amendment, filed 03/17/09 the following rejections remain

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

*(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.*

*(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 37(c) of this title before the invention thereof by the applicant for patent.*

4. Claims 68-81 stand rejected under 35 U.S.C. 102(b) as being anticipated by Simmons et al (IDS) as evidence from the teaching instant Specification on page 26 for the same reasons set forth in the previous Office Action, mailed on 09/12/08.

Applicant's arguments, filed 9/25/00 (Paper No. 10), have been fully considered, but have not been found convincing.

Applicant asserts that : (i) enrichment for 3G5 positive cells does not occurred inherently in the method described in Simmons et al; (ii) Simmons et al., describe enrichment of Srto-1<sup>bright</sup> cells from haemopoietic tissue, but nowhere does Simmons et al., suggest enriching for 3G5 positive cells.

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As initial matter it is noted that , the arguments of counsel cannot take the place of evidence in the record. *In re Schulze* , 145 USPQ 716, 718 (CCPA 1965). See MPEP 716.01©

Examples of attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration include statements regarding unexpected results, commercial success, solution of a long - felt need, inoperability of the prior art, invention before the date of the reference, and allegations that the author(s) of the prior art derived the disclosed subject matter from the applicant.

With regards to Applicant's comments that "enrichment for 3G5 positive cells does not occurred inherently in the method described in Simmons et al".

It is noted that the instant claimed are drawn to a product, i.e. a population of mesenchymal cells precursor enriched for 3G5 positive cells and the patentability of the product does not depend on its method of production. *In re Thrope*, 227 USPQ 964, 966 (Fed. Cir. 1985). See MPEP 2113. In the instant case, the issue is whether the cell population taught by Simmons et al., would inherently be enriched for 3G5 positive cells. Applicant acknowledge that Simmons et al., describe enrichment of Srto-1<sup>bright</sup> cells from hemopoietic tissue ( see Applicant's response mailed on 03/17/09). The instant Specification explicitly teaches that cell surface antigen, 3G5 is highly expressed by the large portion of hematopoietic marrow cells. Thus, it is the Examiner position that the cell population taught by Simmons et al., would inherently be enriched for 3G5 positive cells.

As has been described previously, Simmonst et al., teach an enriched cell population of mesenchymal precursors cells that are capable of giving rise to CFU-F and composition comprising said cells ( see entire document, page 272 and Fig.2 in particular). Simmonst et al., teach that said enriched cell population carry the antigen identified by STRO-1 antibody and that said cells are also positive for VCAM, LFA-3, THY-1, P-selectin, L-selectin, CD49b/CD29 surface markers ( see Table 1 in particular). Simmonst et al., teach that said cells are capable of differentiation into at least adipocytes, osteoblasts and fibroblast ( see Fig.1 in particular). Although the reference is silent about that said enriched cell population of mesenchymal precursors are positive for cell markers 3G5 or MUC18/cd146, as recited in claims 71-76, or positive for one or more markers, recited in claim 77, or negative for the markers recited in claim 78, or capable of forming a clonogenic colony, as recited in claims 80 and 81 these limitation would be inherent properties of the referenced cell composition because the referenced cell composition is the same as claimed. Since the office does not have a laboratory to test the reference enriched cell population, it is applicant's burden to show that the reference cell population does not have the same properties as recited in the claims. See *In re Best*, 195 USPQ 430, 433 (CCPA 1977); *In re Marosi*, 218 USPQ 289, 292-293 (Fed. Cir. 1983); *In re Fitzgerald et al.*, 205 USPQ 594 (CCPA 1980).

Claims 70 and 79 are included because the claimed functional limitation would be inherent properties of the referenced enriched cell population and composition comprising said cells. A

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cell population is a cell population irrespective of their intended use or method of obtaining in the absence of evidence of structural difference.

The reference teaching anticipates the claimed invention.

5. Claims 68-81 stand rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 7,122,178(IDS) or US Patent Application 2005/0281790 or WO 01/04268 for the same reasons set forth in the previous Office Action, mailed on 09/12/08.

Applicant's arguments, filed 9/25/00 (Paper No. 10), have been fully considered, but have not been found convincing.

Applicant asserts that : (i) enrichment for 3G5 positive cells does not occurred inherently in the method described in US Patent'178 or US Patent Application 2005/0281790 or WO 01/04268.

As initial matter it is noted that , the arguments of counsel cannot take the place of evidence in the record. In re Schulze , 145 USPQ 716, 718 (CCPA 1965). See MPEP 716.01©

Examples of attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration include statements regarding unexpected results, commercial success, solution of a long - felt need, inoperability of the prior art, invention before the date of the reference, and allegations that the author(s) of the prior art derived the disclosed subject matter from the applicant.

With regards to Applicant's comments that "enrichment for 3G5 positive cells does not occurred inherently in the method described in US Patent'178 or US Patent Application 2005/0281790 or WO 01/04268.

It is noted that the instant claimed are drawn to a product, i.e. a population of mesenchymal cells precursor enriched for 3G5 positive cells and the patentability of the product does not depend on its method of production. In re Thrope, 227 USPQ 964,966 (Fed. Cir. 1985). See MPEP 2113. In the instant case, the issue is whether the cell population taught in US Patent'178 or US Patent Application 2005/0281790 or WO 01/04268 would inherently be enriched for 3G5 positive cells. The instant Specification explicitly teaches that cell surface antigen, 3G5 is highly expressed by the large portion of hematopoietic marrow cells. Thus, it is the Examiner position that the cell population taught in US Patent'178 or US Patent Application 2005/0281790 or WO 01/04268 would inherently be enriched for 3G5 positive cells.

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US Patent '178 teaches an enriched cell population of mesenchymal precursors cells, wherein said composition are enriched for STRO-1<sup>bright</sup> cells and wherein said cells are capable of giving rise to CFU-F ( see entire document, claims 1-13 in particular). ). Although the reference is silent about that said enriched cell population of mesenchymal precursors are positive for cell markers 3G5 or MUC18/cd146, as recited in claims 71-76, or positive for one or more markers, recited in claim 77, or negative for the markers recited in claim 78, or capable of forming a clonogenic colony, as recited in claims 80 and 81 these limitation would be inherent properties of the referenced cell composition because the referenced cell composition is the same as claimed. Since the office does not have a laboratory to test the reference enriched cell population, it is applicant's burden to show that the reference cell population does not have the same properties as recited in the claims. See *In re Best*, 195 USPQ 430, 433 (CCPA 1977); *In re Marosi*, 218 USPQ 289, 292-293 (Fed. Cir. 1983); *In re Fitzgerald et al.*, 205 USPQ 594 (CCPA 1980).

Claims 70 and 79 are included because the claimed functional limitation would be inherent properties of the referenced enriched cell population and composition comprising said cells. A cell population is a cell population irrespective of their intended use or method of obtaining in the absence of evidence of structural difference.

US Patent Application '790 teaches an enriched cell population of mesenchymal precursors cells, wherein said composition are enriched for STRO-1<sup>bright</sup> cells and wherein said cells are capable of giving rise to CFU-F ( see entire document, claims 52-78 in particular). ). Although the reference is silent about that said enriched cell population of mesenchymal precursors are positive for cell markers 3G5 or MUC18/cd146, as recited in claims 71-76, or positive for one or more markers, recited in claim 77, or negative for the markers recited in claim 78, or capable of forming a clonogenic colony, as recited in claims 80 and 81 these limitation would be inherent properties of the referenced cell composition because the referenced cell composition is the same as claimed. Since the office does not have a laboratory to test the reference enriched cell population, it is applicant's burden to show that the reference cell population does not have the same properties as recited in the claims. See *In re Best*, 195 USPQ 430, 433 (CCPA 1977); *In re Marosi*, 218 USPQ 289, 292-293 (Fed. Cir. 1983); *In re Fitzgerald et al.*, 205 USPQ 594 (CCPA 1980).

Claims 70 and 79 are included because the claimed functional limitation would be inherent properties of the referenced enriched cell population and composition comprising said cells. A cell population is a cell population irrespective of their intended use or method of obtaining in the absence of evidence of structural difference.

The reference teaching anticipates the claimed invention.

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6. Claims 68-81 are directed to an invention not patentably distinct from claims 1-13 of commonly assigned US 7,122,178 . Specifically, claims 1-13 of commonly assigned US 7,122,178 recites population of mesenchymal precursor cells, enriched for STRO-1<sup>bright</sup> cells, capable of giving rise to CFU-F.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned US '178 , discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

Applicant asserts that the method of isolation Srto-1<sup>bright</sup> cell would not inherently result in a population of MPCs enriched for 3G5.

As has been discussed supra, it is the examiner position that an enriched isolated Srto-1<sup>bright</sup> cell taught in US Patent' 178 would inherently be enriched for 3G5 positive cells.

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the

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conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 68-81 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of US Patent 7,122,178. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-13 of US Patent 7,122,178 recited an enriched cell population, of mesenchymal precursor cells, enriched for STRO-1<sup>bright</sup> cells, capable of giving rise to CFU-F. Although the reference is silent about that said enriched cell population of mesenchymal precursors are positive for cell markers 3G5 or MUC18/cd146, as recited in claims 71-76, or positive for one or more markers, recited in claim 77, or negative for the markers recited in claim 78, or capable of forming a clonogenic colony, as recited in claims 80 and 81 these limitation would be inherent properties of the referenced cell composition because the referenced cell composition is the same as claimed.

Claims 70 and 79 are included because the claimed functional limitation would be inherent properties of the referenced enriched cell population and composition comprising said cells. A cell population is a cell population irrespective of their intended use or method of obtaining in the absence of evidence of structural difference.

Applicant asserts that the method of isolation Srto-1<sup>bright</sup> cell would not inherently result in a population of MPCs enriched for 3G5.

As has been discussed supra, it is the examiner position that an enriched isolated Srto-1<sup>bright</sup> cell taught in US Patent' 178 would inherently be enriched for 3G5 positive cells.

9. Claims 68-81 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 52-78 of copending Application No. 11/169875. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 52-78 of copending Application No. 11/169875 recited an enriched cell population, of mesenchymal precursor cells, enriched for STRO-1<sup>bright</sup> cells. Although the reference is silent about that said enriched cell population of mesenchymal precursors are positive for cell markers 3G5 or MUC18/cd146, as recited in claims 71-76, or positive for one or more markers, recited in claim 77, or negative for the markers recited in claim 78, or capable of forming a clonogenic colony, as recited in claims 80



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and 81 these limitation would be inherent properties of the referenced cell composition because the referenced cell composition is the same as claimed.

Claims 70 and 79 are included because the claimed functional limitation would be inherent properties of the referenced enriched cell population and composition comprising said cells. A cell population is a cell population irrespective of their intended use or method of obtaining in the absence of evidence of structural difference.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

It is noted that Applicant indicated that he will address said issue when the subject matter of the instant claims will be found allowable.

10. Claims 68-81 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 59-65 of copending Application No. 10/553633. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 59-65 of copending Application No. 10/553633 recited an isolated human stem cells population, wherein said cells expressed SRTO-1. Although the reference is silent about that said enriched cell population of mesenchymal precursors are positive for cell markers 3G5 or MUC18/cd146, as recited in claims 71-76, or positive for one or more markers, recited in claim 77, or negative for the markers recited in claim 78, or capable of forming a clonogenic colony, as recited in claims 80 and 81 these limitation would be inherent properties of the referenced cell composition because the referenced cell composition is the same as claimed.

Claims 70 and 79 are included because the claimed functional limitation would be inherent properties of the referenced enriched cell population and composition comprising said cells. A cell population is a cell population irrespective of their intended use or method of obtaining in the absence of evidence of structural difference.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

It is noted that Applicant indicated that he will address said issue when the subject matter of the instant claims will be found allowable.

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11. No claim is allowed.

12. **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskyi whose telephone number is 571/272-0840. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571/272-0735.

The fax number for the organization where this application or proceeding is assigned is 571/273-8300

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Michail A Belyavskyi/  
Primary Examiner, Art Unit 1644

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